



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 16 1999

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Edward B. Frankel, M.D.
434 S. Euclid Street
Anaheim, CA 92802-1247

Re: Docket No. 99P-0340/CP1

Dear Dr. Frankel:

This letter responds to your citizen petition dated January 29, 1999, asking the Food and Drug Administration to allow a limited exemption for epinephrine (1:1000 - 1 cc in a pre-loaded syringe with needle) for emergency use. We believe that making epinephrine injections available over the counter would decrease, rather than increase safety, and thus we are denying your petition.

Epinephrine injection kits are available by prescription to people who know that they are at risk of having an anaphylactic/anaphylactoid reaction. A person who gets a prescription for such a kit from his or her doctor gets more than just the prescription. He or she gets counseling on when to use the injection, how to use it, the potential side effects of epinephrine, and how to avoid potential triggers. People who have had a systemic reaction to an insect sting often receive venom immunotherapy from their doctors as well. It would be less safe for at-risk persons to buy epinephrine injections over the counter because they would not be getting counseling by a doctor, nor would they have the opportunity for venom immunotherapy.

Providing epinephrine injections over the counter would not increase safety for persons who are potentially at risk of having an anaphylactic/anaphylactoid reaction, but who have never had such a reaction, because there is no reliable screening method to identify these individuals.

Finally, a NIH Consensus Development Conference on Emergency Treatment of Insect Sting Allergy held in 1978 considered the idea of making epinephrine injections available OTC. The NIH panel concluded that without individualized instruction there was considerable potential for inappropriate use of epinephrine.

For the reasons discussed above, your petition is denied.

Sincerely yours,

Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research

99P-0340

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